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**REMARKS**

**I. Petition for Extension of Time**

Applicant herewith petitions the Commissioner for Patents to extend the time for response to the Office Action mailed 17 January 2007 for three (3) months from 17 April 2007 to 17 July 2007. Authorization is given to charge the extension of time fee of \$1020.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

**II. Claim amendments**

Claims 1-4 have been amended to clarify the claimed invention and describe the surface active agent. Support is provided by paragraphs [0058]-[0064] of the published patent application US 2005-0238719 A1.

Applicant submits that no new matter has been introduced by the claim amendments.

**III. Claim Rejections – 35 U.S. C. §102**

Claims 3 and 5 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by the publication to Petereit et al., European Journal of Pharmaceutics and Biopharmaceutics, Vol. 41, No. 4, pp. 219-228 ("Petereit").

Petereit discloses film-coating compositions containing Eudragit and GMS. Petereit describes GMS as an antisticking agent (Petereit at paragraph 2.3) and as a lipophilic surfactant (Petereit at paragraph 2.4).

Anticipation requires that all the elements of the claimed invention are present and interacting in the same way in a single prior art reference.

The claims have been amended to clarify the claimed invention and describe the surface active agent. According to the amended claims, GMS cannot be both the anti-sticking agent and the surface active agent as taught by Petereit. As such, Petereit fails to anticipate the claimed invention.

Withdrawal of the §102 rejection is requested.

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#### **IV. Claim Rejections – 35 U.S. C. §103**

Claims 3 and 5-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over Petereit in view of US 6,827,947 to Löfroth et al. ("Löfroth").

The subject application has a priority date of 1 August 2002. Löfroth is a §371 application, having a §371(c) date of 16 June 2003, of a PCT application having a filing date of 18 December 2002 and a publication date of 26 June 2003. Accordingly, Löfroth does not qualify as prior art relative to the subject application. As such, the cited combination of Petereit and Löfroth fails to support the obviousness rejection. A *prima facie* case of obviousness has not been established.

Withdrawal of the §103 rejection is requested.

#### **V. Restriction Requirement**

In the interest of administrative economy, Applicant respectfully requests the Examiner to exercise his discretion and reconsider the restriction requirement which has been made final.

For the reasons given above, Petereit no longer supports the restriction requirement of record. According to 37 C.F.R. §1.475(a), the requirement of unity of invention shall be fulfilled when there is a technical relationship among the claims involving one or more special technical features that "define a contribution" over the prior art. The common technical feature in all of the restricted groups is a formulation comprising (i) an ethyl acrylate/methyl methacrylate copolymer, (ii) an anti-sticking agent and (iii) a surface active agent. As defined by the amended claims, GMS cannot be both the anti-sticking agent and the surface active agent as taught by Petereit. The recitation of each and every one of claims 1-16 is characterized by components (i), (ii) and (iii). This combination of ingredients (i), (ii) and (iii) is the special technical feature running throughout and linking the claims. And it is this combination of ingredients which distinguishes the claimed invention and defines a contribution over the cited prior art.

Furthermore, according to 37 C.F.R. §1.475 (b)(1), "...a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product". The subject

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application contains a combination of categories, i.e., product and process, which have been restricted as follows:

Group I – claims 1, 10, 11 and 14 drawn to a film coating composition;

Group II – claims 2 and 15 drawn to a film coat covering a pharmaceutical core;

Group III – claims 3 and 5-9 drawn to a pharmaceutical formulation;

Group IV – claims 4 and 5-9 drawn to a pharmaceutical formulation comprising a plurality of beads;

Group V – claims 3, 12 and 16 drawn to a process for preparing a pharmaceutical formulation comprising a dispersion; and

Group VI – claims 4 and 13 drawn to process for preparing a pharmaceutical formulation comprising coating each bead with a film coating composition wherein the composition comprises a dispersion.

With specific regard to Groups III and IV, the restriction of these two groups makes no sense in view of the fact that the composition of the formulation of Groups III and IV is identical. Patentability does not reside with the shape or form of the formulation but rather with the composition of the formulation. It is expected that the prior art search and examination would be the same for both Groups III and IV. Furthermore, 37 C.F.R. §1.475(b)(1) expressly provides that there is unity of invention with respect to claims drawn to a product and a process for making that product. Groups III and V and Groups IV and VI are related as product and process.

In view of the claim amendments and fact that Petereit no longer supports the restriction requirement or record, Applicant respectfully requests the Examiner to exercise his discretion and reconsider the restriction requirement. In view of 37 C.F.R. §1.475(b)(1), there is at least unity of invention between Groups III-VI, i.e., a product and a process specially adapted for the manufacture of said product.

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CONCLUSION

Applicant has made a good faith attempt to respond to the Office Action. Petereit fails to anticipate claims 3 and 5. Löfroth does not qualify as prior art relative to the subject application. As such, the cited combination of Petereit and Löfroth fails to support the obviousness rejection of claims 3 and 5-9. Applicant requests reconsideration of the restriction requirement. If the Examiner will not withdraw the restriction requirement and exam all of pending claims 1-16, Applicant relies on 37 C.F.R. §1.475(b)(1) and requests at least the rejoinder of the related product and process claims of Groups III-VI.

Any fee due in connection with this communication should be charged to Deposit Account No. 23-1703.

Dated: 16 July 2007

Respectfully submitted,

  
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